REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 25-39 are pending in the application. Independent claim 25 has been amended so that the controlled release composition is in a solid form. Support for this change may be found in the present specification at page 8, line 18 and in Examples 1-14.

In the outstanding Official Action, claims 25-39 were rejected under 35 USC §103(a) as allegedly being obvious over HAUER et al. or COTTENS et al. These rejections are respectfully traversed.

HAUER discloses a galenic system capable of forming microemulsions spontaneously on contact with water alone (see column 6, lines 25-30). The HAUER composition is defined as a micro-emulsion preconcentrate formulation.

While the examples reported in HAUER describe preparations in a liquid form, these liquid preparations are used to fill compositions such as gelatin capsules (see Example 7). Therefore, the compositions described in HAUER remain liquid compositions.

COTTENS discloses micro-emulsion preconcentrate preparations and define the preparation as follows: "...a

composition which spontaneously form a microemulsion in an aqueous medium as water or gastric juice..." (see page 2 bottom).

The examples in COTTENS describe preparations in liquid form which are used to fill gelatin capsules or used as drink solutions. Hence, the COTTENS' formulations are liquid.

A "micro-emulsion" is a clear, stable, isotropic liquid mixtures of oil, water and a surfactant which forms upon mixing two immiscible phases (oil and water). Then, such a structure is thermodynamically stabilized by the surfactant and are dominated by the elastic properties of the surfactant film, as reported by Wikipedia (see Enclosure 1).

On the contrary, the present invention describes an oral solid controlled-release composition formulated with a matrix structure. The term "matrix" is well known in the art as identifying a solid structure, as clearly reported in the here-enclosed copy of the Review of Pharmaceutical Controlled Release Methods the term "matrix" where the matrix devices are identified as "monolithic devices" (see Enclosure 2).

Thus, both publications stand in contrast to the claimed invention, wherein the controlled release composition is in solid form.

This is particularly apparent when considering that the problem solved by both the publications is to provide a composition able to reduce the difficulties in administering

active ingredients that normally present problems of stability, bioavailability and variability.

Neither HAUER nor COTTENS discloses or suggests a controlled or modified release composition able to control the release profile of the drug modulating the dissolution rate of the active principle as recited in the claimed invention.

The Examiner is reminded that a critical step in analyzing obviousness pursuant to 35 U.S.C. §103(a) is casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, only guided by the publications and then-accepted wisdom in the field. Close adherence to this methodology is important in cases where the invention itself may prompt an Examiner to "fall victim to the insidious effect of a hindsight syndrome, wherein that which only the invention taught is used against its teacher." Indeed, to establish a prima facie case of obviousness, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *In re Kotzab,* 217 F.3d 1365, 1369-70, 55 USPQ 2d 1313, 1362 (Fed. Circ. 2000). The fact that the prior art could be so modified would not have made the modification itself obvious unless the cited publications themselves suggested the desirability of the modification. *In re Gordon,* 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Circ. 1984).

In light of the lack of a motivation, suggestion or teaching of the desirability of making the claimed combination, applicant believes that the publication fails to disclose or suggest the claimed invention.

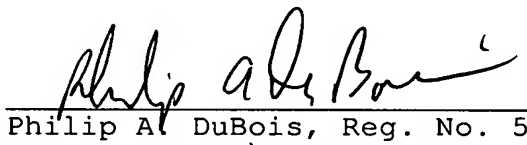
Thus, in view of the above, applicants respectfully request that the rejection be withdrawn.

In view of the present amendment and the foregoing remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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Appendix:

The Appendix includes the following items:

- Enclosure 1 - Excerpt from Wikipiedia relating to microemulsions

- Enclosure 2 - Review of Pharmaceutical Controlled Release Methods and Devices by Paul A. Steward